MEDICAL CHOICE

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October 5, 1999

Dockets Management Branch (HFA - 305)
Food & Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD, 20852

Dear Sir/Madam:

Re: Docket Number (98N-1215)

My letter is in response to the recent FDA proposal to change regulations for foreign establishment registrations and listings. The most recent proposal would require establishments to register with the FDA and then to obtain and identify a US agent. The latter requirement will cause hardship for small companies such as my own. My company may not be able to bear the financial burden of yet another licence or registration fee.

I was contacted by a number of firms and/or individuals offering to register "an agent" when this proposal was first made. There was to be a registration charge and then an annual fee--this was in addition to any actual work done for an inquiry from the FDA that the agent would be responsible for.
My company is small and exports only two products to the United States (both are classified as type II but almost type I in possible risk or dysfunction). I doubt that I would ever really need an agent to represent my company when I read about what the agent's responsibility would be. I want my company to survive and to be able to serve the loyal customers that we have. I also hope that I will eventually be able to introduce more products to the marketplace.

I have two suggestions:

If a company is small, as defined by total sales or number of people employed, one agent could represent many of these small companies and then the shared costs would be minimal.

Another arrangement would have small companies provide the FDA with a toll-free phone number and a contact person within the company who spoke perfect English. There would be no cost to the FDA and any information would be readily available. Also, a small company would not have to pay yet another fee. I prefer the second option.

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98N-1215

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I understand that the FDA deals with numerous products imported from many different companies whose employees may not speak English. However, if the proposal applied to a small company located in an English speaking country, the FDA would be able to satisfy its requirements at a minimal charge to the company.

In summary, I would appreciate a more simple and less costly arrangement. I hope you will voice my concern and I would be happy to hear of other proposals that may have been suggested.

Yours sincerely,

Jan M. Saksun, M.D.

JMS:fl